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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/771,796 | 01/29/2001 | Jacob N. Wohlstadter | 100405-02250 | 7838 |

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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
919 THIRD AVENUE
NEW YORK, NY 10022

EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,796

Applicant(s)

WOHLSTADTER ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-126 and 135-177 is/are pending in the application.
- 4a) Of the above claim(s) 177 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-126 and 135-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 7/8/2004 has been received and entered into record.

The following information provided in the amendment affects the instant application:

1. Claims 1-109, 127-134 are cancelled.
2. Claims 135-177 are added to the instant application.

Restriction/Election

1. Newly submitted claim 177 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submit claim 177 directs to a method for detecting or measuring analyte in an electrochemiluminescence assay using the multi-well plate of claim 110. However, the method claims have been cancelled and applicant chose to pursue apparatus claims instead (Filed on 3/10/2003).

2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 177 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Currently, claims 110-126, 135-176 are under examination. Claim 177 is withdrawn from furthermore consideration.

Objection

4. Claim 111 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 113. When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 110-114, 118-120, 135-145, 155-161, 170 are rejected under 35 U.S.C. 102(b) as being anticipated by Weetall et al. (US 5066372).

Weetall et al. teach a sensor for detecting analytes in test sample. Weetall et al. teach placing the samples in a plurality of wells where each well contains independently addressable electrodes (component 22) and counter electrode (component 24) in each well (See Figure 1 and 2; Col. 2, line 42-55). There is a non-conductive layer (component 40) as a mask having plurality of holes sealed against the said electrode (See Figure 1, Col. 2, line 40-55). The composition of the electrode is of graphite, i.e. carbon (Col. 2, line 37-40). The apparatus contains a standard format of 12 multi-wells for detecting test samples (See Figure 3 and Figure 4).

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7. Claims 110, 112, 117, 119-121, 124-6, 135-7, 141-2, 152-154, 156-171, 174-177 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al. (US 5605662).

Heller et al. disclose a device to concentrate analytes for DNA hybridization. The apparatus comprising a plurality of multi-wells where each well contains independently addressable electrodes centered at the bottom of said wells (See component 62 in Figure 6). A mask of plurality of sealed holes are used to against the electrodes (Col. 6, See the top layer cover the electrodes). The assay can be done in a standard format 96-well plates (Figure 5-6). The diameter for the electrode holes is around 1 mm, so electrode smaller than 1 mm diameter can fit into the holes. (Col. 14, line 45-49). Heller et al. also teach using fluoresence dye, ethidium bromide (EB) for detecting DNA by changes of fluorescence detected by light detector. (Col. 25, line 54-60; Col. 27, line 1-28).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 115-6, 146-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller or Weetal in view of Rourke et al. (US 4720910).

Weetal and Hiller references have been discussed but are silent in teaching use of electrodes comprising a composite material including a polymeric material and carbon particles. Rourke et al. teach a method of efficient utilization of electrode. Rourke et al. teach using a composite comprising the electrode material, a polymeric electrolyte, and an electronically conducting medium such as graphite, e.g. carbon particle (Col. 1, line 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided either Weetal or Heller et al. with the composite material as taught by Rourke et al. for the electrodes since it is known in the art to increase electrode utilization efficiency using the composite materials.

11. Claims 122-123, 172-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. in view of Siddigi et al. (US 554113).

Heller et al. reference has been discussed but is silent in teaching use of metal-containing organic compound for electrochemiluminescent label. Siddigi et al. teach using an electrochemiluminescent method for detecting an analyte in an aqueous solution by using organometallic complexes, including ruthenium, osmium, rhodium for the benefits of maintaining thermal, chemical and photochemical stability, high and long emission lifetimes. (Col. 2, line 27-36) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Heller et al. with the an alternative chemiluminescence methodologies as taught by Siddigi et al. because the organometallic compounds are well-known in the art for maintaining thermal, chemical stability as well as achieving high and long emission lifetimes.

Response to Applicant's Arguments

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12. Applicant's arguments with respect to claims 100-126 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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September 13, 2004


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/20/04